

**IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

v.

ORTHOPAEDIC SOLUTIONS, INC.

Defendant.

Case No. 13-00101-02-CR-W-HFS

PLEA AGREEMENT

Pursuant to Rule 11(c)(1)(B) of the Federal Rules of Criminal Procedure, the parties described below have entered into the following plea agreement:

1. The Parties. The parties to this agreement are the United States Attorney's Office for the Western District of Missouri (otherwise referred to as "the Government" or "the United States"), represented by Tammy Dickinson, United States Attorney, and Jane Pansing Brown, Assistant United States Attorney, and the Orthopaedic Solutions, Inc. ("the defendant"), represented by Bill T. Walker.

The defendant understands and agrees that this plea agreement is only between it and the United States Attorney for the Western District of Missouri, and that it does not bind any other federal, state, or local prosecution authority or any other government agency, unless otherwise specified in this agreement.

2. Defendant's Guilty Plea. The defendant agrees to and hereby does plead guilty to Count Three of the superseding indictment, charging it with a violation of 21 U.S.C. §§ 331(a) and 333(a)(2) and 18 U.S.C. § 2, introduction into interstate commerce of a misbranded drug with intent to defraud and mislead, in that Orthopaedic Solutions, Inc., aided and abetted by others, caused the introduction of a prescription drug into interstate commerce – specifically,

foreign Botox – that was misbranded within the meaning of: (i) 21 U.S.C. § 352(f)(1) in that its labeling failed to bear adequate directions for use; (ii) 21 U.S.C. § 352(f)(2) in that its labeling failed to bear adequate warnings; and (iii) 21 U.S.C. § 353(b)(4)(A) in that its label failed to bear the symbol “Rx only.” By entering into this plea agreement, defendant admits that it knowingly committed this offense, and is in fact guilty of this offense. The government agrees to dismiss counts one, two and four through eleven of the superseding indictment.

3. Factual Basis for Guilty Plea. The parties agree that the facts constituting the offense to which Orthopaedic Solutions, Inc. is pleading guilty are as follows:

On or about August 19 and August 20, 2009, in Kansas City, Jackson County, in the Western District of Missouri, and elsewhere, defendant, Orthopaedic Solutions, Inc. aided and abetted by others, caused the introduction of a prescription drug into interstate commerce – specifically, foreign Botox – that was misbranded within the meaning of: (i) 21 U.S.C. § 352(f)(1) in that its labeling failed to bear adequate directions for use; (ii) 21 U.S.C. § 352(f)(2) in that its labeling failed to bear adequate warnings; and (iii) 21 U.S.C. § 353(b)(4)(A) in that its label failed to bear the symbol “Rx only.”

Specifically, between on or about August 19 and 20, 2009, in Kansas City, in the Western District of Missouri, and elsewhere, Orthopaedic Solutions, located at 1200 East Broadway in Alton, IL, 62002, knowingly caused to be sent and delivered by a commercial interstate carrier, FedEx, foreign Botox¹, a biological product and drug that the Federal Drug Administration had not approved.

¹ In 1989, FDA approved Botox®, the brand name of a drug manufactured by Allergan, Inc., for the treatment of crossed eyes and spasm of the eyelids. Botox® was made up of the Type A toxin, which is highly potent and potentially dangerous and can cause botulism when present in human beings in a sufficient amount. Botulism results in weakness and paralysis that severely affects, among other things, the muscles that control breathing. Severe botulism generally resulted in death. On July 31, 2009, the FDA approved several revisions to the labeling for Botox and Botox Cosmetic, including: (a) the addition of a "boxed warning" (sometimes referred to as a "black box warning") under 21 C.F.R. § 201.57(c)(1) cautioning that the effects of Botox and Botox Cosmetic may spread from the area of injection to other areas of the body, causing symptoms similar to those of botulism; and (b) a revision to the established name of the drug product (from "Botulinum toxin type A" to "OnabotulinumtoxinA") in order to emphasize that the different botulinum toxin products are not interchangeable because the units used to measure the products are different.

From June 22, 2009 through approximately December 21, 2010, Food and Drug Administration (FDA) agents, in an undercover capacity, purchased Botox and Juvederm from Orthopaedic Solutions, its officers, employees and agents.

The Botox received was not labeled for use in the United States. Rather, it was labeled for use in the United Kingdom, United Arab Emirates, Bahrain, Kuwait, Lebanon, Oman, Palestine or other countries. The labeling for these items did not include “Rx only” or the FDA required black box warning for the “Distant Spread of Toxin Effect.”²

On August 19, 2009, FDA SA Steve DeZeeuw ordered one package of Botox by Allergan, Inc., directly from Orthopaedic Solutions via email address orthosol@aol.com. The Botox was received on August 20, 2009, bearing lot number C2388. The return address on this package was Centrino Business Service, Surrey, UK. Allergan, Inc. confirmed this lot of Botox was labeled for distribution in Great Britain.

Between 2008 and 2011, approximately 5,879 units of foreign Botox, Juvederm 2, and Juvederm 3 were distributed by Orthopaedic Solutions through its officers, employees or agents to doctors or other health care professionals in the United States, at a retail value of approximately \$3,058,183.45.

4. Use of Factual Admissions and Relevant Conduct. The defendant acknowledges, understands and agrees that the admissions contained in Paragraph 3 and other portions of this plea agreement will be used for the purpose of determining its guilt and advisory sentencing range under the United States Sentencing Guidelines (“U.S.S.G.”), including the calculation of the defendant’s offense level in accordance with U.S.S.G. § 1B1.3(a)(2). The defendant acknowledges, understands and agrees that the conduct charged in any dismissed counts of the indictment as well as all other uncharged related criminal activity shall be considered as “relevant conduct” pursuant to U.S.S.G. § 1B1.3(a)(2) in calculating the offense level for the charge to which it is pleading guilty.

² During the course of this investigation, FDA SA Joseph McCulley (McCulley) spoke with Allergan representatives regarding Botox labeling in the United States. Representatives stated one difference between the U.S. label and other countries is the FDA required “black box warning.” This warning advises users of the possibility of “Distant Spread of Toxin Effect” in bold type outlined in a black box. No FDA required “black box warning” was located on any of the Botox labels received through the undercover purchases.

5. Statutory Penalties. The defendant understands that upon its plea of guilty to Count Three of the superseding indictment charging it with violating 22 U.S.C. §§ 331(a) and 333(a)(2) and 18 U.S.C. § 2, the maximum penalty the Court may impose is not more than a \$500,000 fine, not more than 5 years of probation, an order of restitution, and a \$400 mandatory special assessment per count of conviction, which must be paid in full at the time of sentencing. The defendant further understands that this offense is a Class E felony.

6. Sentencing Procedures. The defendant acknowledges, understands and agrees to the following:

a. in determining the appropriate sentence, the Court will consult and consider the United States Sentencing Guidelines promulgated by the United States Sentencing Commission; these Guidelines, however, are advisory in nature, and the Court may impose a sentence either less than or greater than the defendant's applicable Guidelines range, unless the sentence imposed is "unreasonable";

b. the Court will determine the defendant's applicable Sentencing Guidelines range at the time of sentencing;

c. the Court may impose a term of probation of up to five years;

d. the Court may impose any sentence authorized by law, including a sentence that is outside of, or departs from, the applicable Sentencing Guidelines range;

e. the Court is not bound by any recommendation regarding the sentence to be imposed or by any calculation or estimation of the Sentencing Guidelines range offered by the parties. The parties waive a pre-sentence report and request the Court sentence the defendant at a date to be established by the Court after the entry of defendant's guilty plea; and

f. the defendant may not withdraw its guilty plea solely because of the nature or length of the sentence imposed by the Court.

g. any sentence of imprisonment imposed by the Court will not allow for parole;

h. The defendant agrees that the United States may institute civil, judicial or administrative forfeiture proceedings against all forfeitable assets in which the defendant has an interest, and that it will not contest any such forfeiture proceedings. The United States agrees it will not institute said proceedings so long as payments are made pursuant to the terms of this agreement.

i. The defendant agrees to fully and truthfully disclose the existence, nature and location of all assets forfeitable to the United States, either directly or as a substitute asset, in which it, or a co-defendant has or had any direct or indirect financial interest, or exercise or exercised control, directly or indirectly. The defendant also agrees to fully and completely assist the United States in the recovery and forfeiture of all such forfeitable assets.

j. The defendant agrees not to contest the transfer of property from any state or local agency to the United States and to take whatever steps are necessary to facilitate that transfer. The defendant specifically agrees and authorizes any state or local law enforcement agency having possession of property subject to federal forfeiture to release the property to a federal agency either prior to or after entry of an order forfeiting the defendant's interest in such property. Further, the defendant agrees to hold harmless any state or local law enforcement agency which releases such property to any federal agency for federal forfeiture proceedings.

k. The defendant agrees to take all necessary steps to comply with the forfeiture matters set forth herein before its sentencing.

l. In the event any federal, state or local law enforcement agency having custody of the forfeitable property in the future decides not to pursue forfeiture of the property due to its minimal value, the defendant hereby abandons any interest it has in such property and consents to the destruction or any other disposition of the property by the federal, state or local agency without further notice or obligation whatsoever owing to the defendant.

m. Within 10 days of the execution of this plea agreement, at the request of the USAO, the defendant agrees to execute and submit (1) a Tax Information Authorization form; (2) an Authorization to Release Information; (3) a completed financial disclosure statement; and (4) copies of financial information that the defendant submits to the U.S. Probation Office. The defendant understands that the United States will use the financial information when making its recommendation to the Court regarding the defendant's acceptance of responsibility.

7. Government's Agreements. Based upon evidence in its possession at this time, the United States Attorney's Office for the Western District of Missouri, as part of this plea agreement, agrees not to bring any additional charges against defendant or Christopher Carstens for any federal criminal offenses related to mail fraud, introduction into interstate commerce of an unapproved new drug with intent to defraud and mislead, introduction into interstate commerce of a misbranded drug with intent to defraud and mislead, introduction into interstate commerce of an adulterated device with intent to defraud and mislead, introduction into interstate commerce of a misbranded device with intent to defraud and mislead and smuggling goods into the United States for which it has venue and which arose out of the defendant's conduct described above.

The defendant understands that this plea agreement does not foreclose any prosecution for an act of murder or attempted murder, an act or attempted act of physical or sexual violence against the person of another, or a conspiracy to commit any such acts of violence or any criminal activity of which the United States Attorney for the Western District of Missouri has no knowledge.

The defendant recognizes that the United States' agreement to forego prosecution of all of the criminal offenses with which the defendant might be charged is based solely on the promises made by the defendant in this agreement. If the defendant breaches this plea agreement, the United States retains the right to proceed with the original charges and any other criminal violations established by the evidence. The defendant expressly waives its right to challenge the initiation of the dismissed or additional charges against it if it breaches this agreement. The defendant expressly waives the right to assert a statute of limitations defense if the dismissed or additional charges are initiated against it following a breach of this agreement.

The defendant further understands and agrees that if the Government elects to file additional charges against it following its breach of this plea agreement, it will not be allowed to withdraw this guilty plea.

8. Preparation of Presentence Report. The defendant understands the United States will provide to the Court and the United States Probation Office a government version of the offense conduct. This may include information concerning the background, character, and conduct of the defendant, including the entirety of its criminal activities. The defendant understands these disclosures are not limited to the count to which it has pleaded guilty. The United States may respond to comments made or positions taken by the defendant or the defendant's counsel and to correct any misstatements or inaccuracies. The United States further reserves its right to make any recommendations it deems appropriate regarding the disposition of this case, subject only to any limitations set forth in this plea agreement. The United States and the defendant expressly reserve the right to speak to the Court at the time of sentencing pursuant to Rule 32(i)(4) of the Federal Rules of Criminal Procedure.

9. Withdrawal of Plea. Either party reserves the right to withdraw from this plea agreement for any or no reason at any time prior to the entry of the defendant's plea of guilty and its formal acceptance by the Court. In the event of such withdrawal, the parties will be restored to their pre-plea agreement positions to the fullest extent possible. However, after the plea has been formally accepted by the Court, the defendant may withdraw its plea of guilty only if the Court rejects the plea agreement or if the defendant can show a fair and just reason for requesting

the withdrawal. The defendant understands that if the Court accepts its plea of guilty and this plea agreement but subsequently imposes a sentence that is outside the defendant's applicable Sentencing Guidelines range, or imposes a sentence that the defendant does not expect, like, or agree with, it will not be permitted to withdraw its plea of guilty.

10. Agreed Guidelines Applications. With respect to the application of the Sentencing Guidelines to this case, the parties stipulate and agree as follows:

a. The Sentencing Guidelines do not bind the Court and are advisory in nature. The Court may impose a sentence that is either above or below the defendant's applicable Guidelines range, provided the sentence imposed is not "unreasonable."

b. The applicable Guidelines section for the offense of conviction for a corporation is U.S.S.G. §8C2.4. The total offense level is 20.

c. The defendant has admitted its guilt and clearly accepted responsibility for its actions, and has assisted authorities in the investigation or prosecution of its own misconduct by timely notifying authorities of its intention to enter a plea of guilty, thereby permitting the Government to avoid preparing for trial and permitting the Government and the Court to allocate their resources efficiently. Therefore, it is entitled to a two-level reduction pursuant to § 3E1.1(a) of the Sentencing Guidelines;

d. The parties acknowledge defendant is a corporation, and therefore not subject to a term of imprisonment.

e. The defendant agrees a forfeiture judgment shall be entered in the amount of \$374,476.50 to the United States Government. \$80,000.00 shall be due at the time of sentencing and \$3,505.68 paid on the first day of each month following 30 days after the sentencing, until paid in full. For example, if sentencing is November 15, 2014, the first payment shall be January 1, 2015. The term of monthly payments shall be 84 months.

e. There is no agreement between the parties regarding the defendant's criminal history category. The parties agree that the Court will determine the applicable criminal history category after receipt of the presentence investigation report prepared by the United States Probation Office.

f. The defendant understands that the estimate of the parties with respect to the Guidelines computation set forth in the subsections of this paragraph does not bind the Court or the United States Probation Office with respect to the appropriate Guidelines levels. Additionally, the failure of the Court to accept these stipulations will not, as outlined in Paragraph 9 of this plea agreement, provide the defendant with a basis to withdraw the plea of guilty.

g. The agreement by the parties is not binding upon the Court or the United States Probation Office and the Court may impose any sentence authorized by law, including any sentence outside the applicable Guidelines range that is not “unreasonable.”

h. The defendant consents to judicial fact-finding by a preponderance of the evidence for all issues pertaining to the determination of the defendant’s sentence, including the determination of any mandatory minimum sentence (including the facts that support any specific offense characteristic or other enhancement or adjustment), and any legally authorized increase above the normal statutory maximum. The defendant waives any right to a jury determination beyond a reasonable doubt of all facts used to determine and enhance the sentence imposed, and waives any right to have those facts alleged in the indictment. The defendant also agrees that the Court, in finding the facts relevant to the imposition of sentence, may consider any reliable information, including hearsay.

i. The defendant understands and agrees that the factual admissions contained in Paragraph 3 of this plea agreement, and any admissions that it will make during the plea colloquy, support the imposition of the agreed-upon Guidelines calculations contained in this agreement.

11. Effect of Non-Agreement on Guidelines Applications. The parties understand, acknowledge and agree that there are no agreements between the parties with respect to any Sentencing Guidelines issues other than those specifically listed in Paragraph 10, and its subsections. As to any other Guidelines issues, the parties are free to advocate their respective positions at the sentencing hearing.

12. Change in Guidelines Prior to Sentencing. The defendant agrees that if any applicable provision of the Guidelines changes after the execution of this plea agreement, then any request by defendant to be sentenced pursuant to the new Guidelines will make this plea

agreement voidable by the United States at its option. If the Government exercises its option to void the plea agreement, the United States may charge, reinstate, or otherwise pursue any and all criminal charges that could have been brought but for this plea agreement.

13. Government's Reservation of Rights. The defendant understands that the United States expressly reserves the right in this case to:

- a. oppose or take issue with any position advanced by defendant at the sentencing hearing which might be inconsistent with the provisions of this plea agreement;
- b. comment on the evidence supporting the charge in the indictment;
- c. oppose any arguments and requests for relief the defendant might advance on an appeal from the sentences imposed and that the United States remains free on appeal or collateral proceedings to defend the legality and propriety of the sentence actually imposed, even if the Court chooses not to follow any recommendation made by the United States; and
- d. oppose any post-conviction motions for reduction of sentence, or other relief.

14. Waiver of Constitutional Rights. The defendant, by pleading guilty, acknowledges that it has been advised of, understands, and knowingly and voluntarily waives the following rights:

- a. the right to plead not guilty and to persist in a plea of not guilty;
- b. the right to be presumed innocent until its guilt has been established beyond a reasonable doubt at trial;
- c. the right to a jury trial, and at that trial, the right to the effective assistance of counsel;
- d. the right to confront and cross-examine the witnesses who testify against it;

- e. the right to compel or subpoena witnesses to appear on its behalf; and
- f. the right to remain silent at trial, in which case its silence may not be used against it.

The defendant understands that by pleading guilty, it waives or gives up those rights and that there will be no trial. The defendant further understands that if it pleads guilty, the Court may ask it questions about the offense or offenses to which it pleaded guilty, and if the defendant answers those questions under oath and in the presence of counsel, its answers may later be used against it in a prosecution for perjury or making a false statement.

15. Waiver of Appellate and Post-Conviction Rights.

a. The defendant acknowledges, understands and agrees that by pleading guilty pursuant to this plea agreement it waives its right to appeal or collaterally attack a finding of guilt following the acceptance of this plea agreement, except on grounds of (1) ineffective assistance of counsel; or (2) prosecutorial misconduct.

b. The defendant expressly waives its right to appeal the sentence, directly or collaterally, on any ground except claims of (1) ineffective assistance of counsel; (2) prosecutorial misconduct; or (3) an illegal sentence. An “illegal sentence” includes a sentence imposed in excess of the statutory maximum, but does *not* include less serious sentencing errors, such as a misapplication of the Sentencing Guidelines, an abuse of discretion, or the imposition of an unreasonable sentence. However, if the United States exercises its right to appeal the sentence imposed as authorized by 18 U.S.C. § 3742(b), the defendant is released from this waiver and may, as part of the Government’s appeal, cross-appeal its sentence as authorized by 18 U.S.C. § 3742(a) with respect to any issues that have not been stipulated to or agreed upon in this agreement.

16. Financial Obligations. By entering into this plea agreement, the defendant represents that it understands and agrees to the following financial obligations:

a. The Court may order restitution to the victims of the offenses to which the defendant is pleading guilty. The defendant agrees that the Court may order restitution in connection with the conduct charged in any counts of the indictment which are to be dismissed and all other uncharged related criminal activity.

b. The United States may use the Federal Debt Collection Procedures Act and any other remedies provided by law to enforce any restitution order that may be entered as part of the sentence in this case and to collect any fine.

c. The defendant will fully and truthfully disclose all assets and property in which it has any interest, or over which the defendant exercises control directly or indirectly, including assets and property held by a spouse, nominee or other third party. The defendant's disclosure obligations are ongoing, and are in force from the execution of this agreement until the defendant has satisfied the restitution order in full.

d. Within 10 days of the execution of this plea agreement, at the request of the USAO, the defendant agrees to execute and submit (1) a Tax Information Authorization form; (2) an Authorization to Release Information; (3) a completed financial disclosure statement; and (4) copies of financial information that the defendant submits to the U.S. Probation Office. The defendant understands that compliance with these requests will be taken into account when the United States makes a recommendation to the Court regarding the defendant's acceptance of responsibility.

e. The defendant hereby authorizes the USAO to obtain a credit report pertaining to it to assist the USAO in evaluating the defendant's ability to satisfy any financial obligations imposed as part of the sentence.

f. The defendant understands that a Special Assessment will be imposed as part of the sentence in this case. The defendant promises to pay the Special Assessment of \$400 by submitting a satisfactory form of payment to the Clerk of the Court prior to appearing for the sentencing proceeding in this case. The defendant agrees to provide the Clerk's receipt as evidence of its fulfillment of this obligation at the time of sentencing.

g. The defendant certifies that it has made no transfer of assets or property for the purpose of (1) evading financial obligations created by this Agreement; (2) evading obligations that may be imposed by the Court; nor (3) hindering efforts of the USAO to enforce such financial obligations. Moreover, the defendant promises that it will make no such transfers in the future.

h. In the event the United States learns of any misrepresentation in the financial disclosure statement, or of any asset in which the defendant had an interest at the time of this plea agreement that is not disclosed in the financial disclosure statement, and in the event such misrepresentation or nondisclosure changes the estimated net worth of the defendant by hundred thousand dollars (\$100,000) or more, the United States may at its option: (1) choose to be relieved of its obligations under this plea agreement; or (2) let the plea agreement stand, collect the full forfeiture, restitution, and fines imposed by any criminal or civil

judgment, and also collect 100% (one hundred percent) of the value of any previously undisclosed assets. The defendant agrees not to contest any collection of such assets. In the event the United States opts to be relieved of its obligations under this plea agreement, the defendant's previously entered pleas of guilty shall remain in effect and cannot be withdrawn.

17. Waiver of FOIA Request. The defendant waives all of its rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case including, without limitation, any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act of 1974, 5 U.S.C. § 552a.

18. Waiver of Claim for Attorney's Fees. The defendant waives all claims under the Hyde Amendment, 18 U.S.C. § 3006A, for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

19. Defendant's Breach of Plea Agreement. If the defendant commits any crimes, violates any conditions of release, or violates any term of this plea agreement between the signing of this plea agreement and the date of sentencing, or fails to appear for sentencing, or if the defendant provides information to the Court that is intentionally misleading, incomplete, or untruthful, or otherwise breaches this plea agreement, the United States will be released from its obligations under this agreement. The defendant, however, will remain bound by the terms of the agreement, and will not be allowed to withdraw its plea of guilty.

The defendant also understands and agrees that in the event it violates this plea agreement, all statements made by it to law enforcement agents subsequent to the execution of this plea agreement, any testimony given by it before a grand jury or any tribunal or any leads from such statements or testimony shall be admissible against it in any and all criminal proceedings. The defendant waives any rights that it might assert under the United States Constitution, any statute, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the

Federal Rules of Evidence, or any other federal rule that pertains to the admissibility of any statements made by it subsequent to this plea agreement.

20. Defendant's Representations. The defendant acknowledges that it has entered into this plea agreement freely and voluntarily after receiving the effective assistance, advice and approval of counsel. The defendant acknowledges that it is satisfied with the assistance of counsel, and that counsel has fully advised it of its rights and obligations in connection with this plea agreement. The defendant further acknowledges that no threats or promises, other than the promises contained in this plea agreement, have been made by the United States, the Court, its attorneys or any other party to induce it to enter a plea of guilty.

21. No Undisclosed Terms. The United States and defendant acknowledge and agree that the above-stated terms and conditions, together with any written supplemental agreement that might be presented to the Court in camera, constitute the entire plea agreement between the parties, and that any other terms and conditions not expressly set forth in this agreement or any written supplemental agreement do not constitute any part of the parties' agreement and will not be enforceable against either party.

22. Standard of Interpretation. The parties agree that, unless the constitutional implications inherent in plea agreements require otherwise, this plea agreement should be interpreted according to general contract principles and the words employed are to be given their normal and ordinary meanings. The parties further agree that, in interpreting this agreement, any drafting errors or ambiguities are not to be automatically construed against either party, whether or not that party was involved in drafting or modifying this agreement.

Tammy Dickinson
United States Attorney

Dated: 6-5-2014

/s/ Jane Pansing Brown
Jane Pansing Brown
Assistant United States Attorney

As President of Orthopaedic Solutions, Inc., I hereby acknowledge Orthopaedic Solutions, Inc. has entered into this plea agreement knowingly and voluntarily with advice of counsel and I have executed this agreement on behalf of Orthopaedic Solutions, Inc. with express authority to do so. Orthopaedic Solutions, Inc. has observed all requirements necessary to permit a corporation to enter into and bind itself by the agreement under which Orthopaedic Solutions, Inc. will plead guilty to the Count Three of the superseding indictment described in the plea agreement. On behalf of Orthopaedic Solutions, Inc., and as its authorized representative, I acknowledge Orthopaedic Solutions, Inc. fully understands the rights of Orthopaedic Solutions, Inc. with respect to the provisions of the sentencing guidelines and the plea agreement.

Dated: 6-5-2014

/s/ Christopher Carstens, President
Orthopaedic Solutions, Inc.

By Christopher Carstens
President
Orthopaedic Solutions, Inc.
Defendant

I am Defendant Orthopaedic Solutions' attorney. I have fully explained to Mr. Christopher Carstens, President of Orthopaedic Solutions, Inc., all rights with respect to the offense charged in the superseding indictment. Further, I have reviewed with him the provisions of the Sentencing Guidelines which might apply in this case. I have carefully reviewed every part of this plea agreement with him. To my knowledge Orthopaedic Solutions' decision, through Mr. Carstens, to enter into this plea agreement is an informed and voluntary one.

Dated: 6-5-2014

/s/ Bill T. Walker
Bill T. Walker
Attorney for Defendant